

REMARKS

A. Background

Claims 35-64, and 92-107 were pending in the application at the time of the Office Action. Claims 35-64, and 92-107 were rejected as being anticipated by and/or obvious over cited art. By this response Applicant has amended claims 35, 49, and 92; and added new claim 108. As such, claims 35-64 and 92-108 are presented for the Examiner's consideration in light of the following remarks.

B. Proposed Amendments

Applicant has herein amended claims 35, 49, and 92 to further clarify, more clearly define, and/or broaden the claimed inventions to expedite receiving a notice of allowance. For example, independent claim 35 has been amended to recite that the means for securing a fastener is configured such that the fastener is rigidly fixed to the body "so as to prevent pivoting movement of the body with respect to the fastener." Similarly, independent claim 49 has been amended to recite that the elongated fastener is configured to rigidly mount to the implant to "prevent pivoting movement of the implant with respect to the fastener." Independent claim 92 has been amended to clarify that the distal end of the fastener is mounted to the implant by threaded engagement "between the implant and the fastener." The amendments to the claims are supported in the application at least by Figures 17 and 22 and the corresponding discussion in the specification. New claim 108 is supported at least by Figures 17 and 22 and the corresponding discussion of the specification. In view of the foregoing, Applicant submits that the amendments to the claims do not introduce new matter and entry thereof is respectfully requested.

C. Rejection based on 35 USC § 102

Page 2 of the Office Action rejects claims 35-41, 43-45, 48-53, 55, 57-64, and 92-107 under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,673,407 to Martin (“*Martin*”). Of the rejected claims, claims 35, 49, and 92 are independent claims. Applicant respectfully traverses this rejection and submits that *Martin* does not anticipate claims 35-41, 43-45, 48-53, 55, 57-64, and 92-107 at least because *Martin* does not include each and every claim limitation recited in the rejected claims.

1. Independent Claims 35, 49, and 92

As noted in the prior response dated January 28, 2008, *Martin* discloses an implant used for joint replacement in a bone. See Abstract. As shown in Figure 1, the *Martin* implant 22 comprises an inner plate member 24 that abuts the resected bone, and an outer joint member that is positioned on the inner plate member 24. See col. 4, lines 49-57. The inner plate member 24 includes wells 34, each having a cap 40 with a hole 42 therein through which a screw 36 can be inserted to attach the implant to the bone. See col. 4, lines 61-67.

The *Martin* screw 36 has an enlarged head 52 on one end and a threaded portion 48 on the other end. The threaded portion 48 of the screw 36 is passed down through hole 42 and then threaded into the bone (or, in a variation, into a plug 78 that is already positioned within the bone) so as to rigidly anchor the screw 36 to the bone. See col. 5, lines 24-29. The threaded portion 48 of the screw 36 is also referred to as the “attachment element,” and the head 52 and body of the screw 36 is referred to as the “connecting member.” See col. 5, lines 29-38. The head 52 of the screw 36 seats the implant 22 against the bone.

According to *Martin*, “[a] key object of this invention is to avoid constraining the transfer of physiologic forces from the subarticular portion of the prosthesis to the adjacent bone.” Col. 6, lines 22-25. Correspondingly, *Martin* discloses that one of the important features of the *Martin* implant is “to allow relative axial and lateral movement of the screw with respect to the implant.” Col. 4, line 68 to col. 5, line 3; see also Abstract, col. 5, line 38-41; col. 10, lines 36-42. To allow for this movement, a spring 56 is positioned between the head 52 of the screw 36 and the cap 40. See Figure 1. This spring 56 allows the implant to move in response to various external forces. See Figures 2-5 and col. 6, line 43 to col. 7, line 24. In an alternative disclosed embodiment, the spring 88 is located in the plug 78 that has already been positioned in the bone and the head of the screw 76 rests against the cap 72 of the implant 62. See Figure 6. In this embodiment, *Martin* discloses that the cap 72 “provides a concave surface which forms the socket in a ball-and-socket joint between the implant and the connecting member, to allow swinging movement of the connecting member with respect to the well.” Col. 8, lines 9-13.

In sum, the *Martin* implant is specifically designed to be pivotal relative to the connecting member that connects the implant to the bone so as to allow certain forces to be transferred to the bone.

Because the connecting member and the implant in *Martin* are pivotal relative to each other, Applicant submits that *Martin* does not disclose or suggest an implant having a body and “means for securing a fastener to the second side of the body after the bone apposition surface is biased against the natural or resected articulating surface such that **the fastener is rigidly fixed to the body so as to prevent pivoting movement of the body with respect to the fastener**,” as recited in amended claim 35. Similarly, Applicant submits that *Martin* does not disclose or suggest an implant system which includes “an elongated fastener **configured to ... prevent**

pivoting movement of the implant with respect to the fastener,” as recited in amended claim

49. In fact, the Examiner concedes in the Office Action that the fastener and the body “are not rigidly fixed together with respect to a movement direction along their axes.” Office Action at p. 4.

Furthermore, because Martin only discloses a threaded connection between the screw and the bone and between the screw and the plug within the bone and further specifically teaches moveable engagement between the screw and the implant, Applicant submits that Martin does not disclose or suggest an implant system having “an elongated fastener ... mounted to the implant by threaded engagement **between the implant and the fastener,**” as recited in amended claim 92. In fact, the Examiner concedes in the Office Action that “if the threaded engagement were clearly defined in terms of ... threaded portions on respective elements of the device, or the like, the ... rejection would likely not apply.” Office Action at p. 4.

In view of the foregoing, Applicant submits that *Martin* does not include each and every limitation recited in claims 35, 49, or 92 and respectfully requests that the anticipation rejection of claims 35, 49, and 92 be withdrawn.

2. Dependent Claims 36-41, 43-45, 48, 50-53, 55, 57-64, and 93-107

Claims 36-41, 43-45, 48, 50-53, 55, 57-64, and 93-107 each depend from one of claims 35, 49, and 92 and thus incorporate the limitations thereof. As such, Applicant submits that claims 36-41, 43-45, 48, 50-53, 55, 57-64, and 93-107 are distinguished over the cited art for at least the same reasons as discussed above with regard to claims 35, 49, and 92. Accordingly, Applicant respectfully requests that the anticipation rejection with respect to claims 36-41, 43-45, 48, 50-53, 55, 57-64, and 93-107 also be withdrawn.

Applicant further submits that many, if not all, of the rejected dependent claims are independently distinguishable over *Martin*. For example, claims 36 and 39 each recite “a blind socket” formed on the implant. In contrast, the wells 34 on the *Martin* implant are necessarily open at both ends so as to form a passage that extends through the implant. This passage is necessary so that the screw 36 can be passed down through well 34 of *Martin* and screwed into the bone. Thus, *Martin* fails to teach “a blind socket” as set forth in claims 36 and 39.

Applicant notes that the same arguments presented above regarding the independent distinguishability of claims 36 and 39 were also presented in the January 28th response but that the Examiner has failed to address or even acknowledge the arguments in the present Office Action. Applicant submits that such an approach to examination is clearly inconsistent with established examination guidelines. Particularly, Applicant notes that “[w]here the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, *take note of the applicant’s argument and answer the substance of it.*” MPEP § 707.07(f). *Emphasis added.* Because the Examiner has failed to do this, Applicant submits that the Office Action has failed to establish anticipation regarding dependent claims 36 and 39 and the anticipation rejection of those claims must be withdrawn.

Other examples of rejected dependent claims that are independently distinguishable over *Martin* include the following:

- Claim 40 recites that the “stem has threads formed thereon;”
- Claims 48 and 55 each recite that the body comprises two separate connectable parts in which each part comprises “a portion of the top articular surface and the bone apposition surface;”

- Claim 50 recites “a stem projecting from the bone apposition surface, the stem being threaded;”
- Claim 51 recites “a socket formed on the bone apposition surface, the socket being threaded;”
- Claim 60 recites “the fastener has at least one helical thread that engages with the implant and the bone anchor has at least one external helical thread, the helical thread of the bone anchor rotating in a direction opposite of the helical thread of the fastener;”
- Claim 64 recites “a drive rod integrally formed with the fastener, a plurality of spaced apart annular breaking grooves being formed at the intersection between the fastener and the drive rod;”
- Claim 94 recites that “the means for securing the fastener comprises a threaded connection disposed or formed on the body of the implant;”
- Claims 95 and 100 each recite that “the means for securing the fastener is configured so as to be inaccessible from the top surface of the tray;”
- Claim 97 recites that “the fastener has at least one helical thread that engages with the implant;”
- Claim 98 recites “means for attaching a fastener driver to the proximal end of the fastener;”
- Claims 102 and 106 each recite “means for attaching an attachment tool to the ... nut;” and
- Claim 103 and 107 each recite that “the means for attaching the attachment tool comprises a plurality of prongs formed on the ... nut.”

Applicant notes that not only are the above-listed limitations not disclosed in *Martin*, but that the Office Action has not even asserted, let alone demonstrated how *Martin* allegedly discloses any of these limitations. However, to establish anticipation for any claim, each and every element as set forth in that claim must be found, either expressly or inherently described, in the single prior art reference. See MPEP § 2131. Because the Office Action has failed to demonstrate that any of the claim elements listed above are found in *Martin*, the Office Action has also failed to establish anticipation regarding those dependent claims and the anticipation rejection of those claims must also be withdrawn.

3. Not obvious to Modify Martin

Applicant further submits that it would not have been obvious to modify the *Martin* implant to include the above identified deficiencies. For example, as noted above, *Martin* discloses that the ability to provide relative movement between the implant and the screw is “an important feature of the invention” to allow the implant to transfer various physiologic forces from the prosthesis to the bone. If the connection between the implant and the screw were changed to be a rigid connection, such as by threaded engagement, this “important feature” of *Martin* would be lost, rendering the Martin implant unsatisfactory for its intended purpose. As is well established, if a modification would render an invention unsatisfactory for its intended purpose, that modification would not have been obvious. See MPEP § 2143.01 (V).

D. Rejection based on 35 USC § 103

Page 3 of the Office Action rejects claims 42 and 56 under 35 USC § 103(a) as being unpatentable over *Martin*. Specifically, the Office Action asserts that it would have been

obvious to use claimed stem and fastener length ranges. Pages 3 and 4 of the Office Action rejects claims 46, 47, and 54 under 35 USC § 103(a) as being unpatentable over *Martin* in view of U.S. Patent No. 4,000,525 to Klawitter et al. (“*Klawitter*”). *Klawitter* is cited simply for allegedly teaching the use of a porous inlay. Applicant respectfully traverses these rejections and submits that even if, *arguendo*, it was obvious to make the aforementioned modifications to *Martin*, the resulting combinations would still not teach or suggest all of the claim limitations.

That is, each of claims 42, 46, 47, 54, and 56 depend from one of claims 35 or 49 and thus incorporate the limitations thereof. As such, Applicant submits that claims 42, 46, 47, 54, and 56 are distinguished over the cited art for at least the same reasons as discussed above with regard to claims 35 and 49. Accordingly, Applicant respectfully requests that the obviousness rejections with respect to claims 42, 46, 47, 54, and 56 be withdrawn.

No other objections or rejections are set forth in the Office Action.

E. New Claims

Applicant submits that new claim 108 is also distinguished over the cited art of record. For example, claim 41 recites “**the fastener has a first helical thread and the implant has a second helical thread and the fastener is rigidly mounted to the implant by threaded connection between the first and second helical threads.**” Applicant submits that none of the cited art, individually or combined, teach or suggest these limitations.

Furthermore, new claim 108 depends from independent claim 49 and thus incorporates the limitations thereof. As such, claim 108 is distinguished over the cited art for at least the reasons given above regarding claim 49.

F. Conclusion

Applicant notes that this response does not discuss every reason why the claims of the present application are distinguished over the cited art. Most notably, applicant submits that many if not all of the dependent claims are independently distinguishable over the cited art. Applicant has merely submitted those arguments which it considers sufficient to clearly distinguish the claims over the cited art.

In view of the foregoing, applicant respectfully requests the Examiner's reconsideration and allowance of claims 35-64 and 92-108 as amended and presented herein.

In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Dated this 12th day of September 2008.

Respectfully submitted,

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